

APPLICANT'S ART CITATION (Use several sheets if necessary)	Application 10/774,358	OGS File No. P/546-279 REISSUE
	Applicant William Stern	
	Filing Date February 5, 2004	Group Art Unit 1616

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U.S. PATENT DOCUMENTS

Examiner Initial	Patent or Trademark Office Number	Date MM-YYYY	Name	Class	Sub-class	Filing Date If Appropriate
M	US-6,087,338	07-2000	Veronesi et al.	514	21	Aug. 8, 1997
	US-6,107,277	08-2000	Veronesi et al.	514	12	Aug. 8, 1997
	US-5,124,315	06-1992	Ceschel et al.	514	12	Jun. 17, 1991
	US-5,183,802	02-1993	Aliverti et al.	514	2	Nov. 14, 1988
	US-5,026,825	06-1991	Grebow et al.	530	307	Sep. 8, 1988
	US-5,759,565	06-1998	Azria et al.	424	434	Dec. 31, 1991
	US-4,788,221	11-1998	Kagatani et al.	514	808	May 5, 1988
	US-5,059,587	10-1991	Yamamoto et al.	514	12	Jun 19, 1998
	US-5,665,700	09-1997	Cho et al.	514	2	Aug 15, 1994
M	US-6,149,893	11-2000	Mardente et al.	424	45	Mar 1, 1999

FOREIGN PATENT DOCUMENTS

	Document Number	Date MM-YYYY	Country	Class	Sub-class	Translation	
						Yes	No
M	0 809 512	12-1997	Europe				
	0 115 627	08-1984	Europe				
	0 418 697	03-1991	Europe				
	0 358 234	03-1990	Europe				
M	0 327 756	08-1989	Europe				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

M	A	Dua et al., International Journal of Pharmaceutics 147, 1997, pp. 233-242 "The influence of tonicity and viscosity on the intranasal absorption of salmon calcitonin in rabbits."
	B	P. Graf et al., Clin. Exp. Allergy, Vol. 25:395-400; 1995 "Benzalkonium chloride in a decongestant nasal spray aggravates rhinitis medicamentosa in healthy volunteers"
	C	H. Hallen et al., Clin. Exp. Allergy, Vol. 25:401-405; 1995 "Benzalkonium chloride in nasal decongestive sprays has a long-lasting adverse effect on the nasal mucosa of healthy volunteers"
	D	Berg et al., Laryngoscope 104:1153-1158; 1994 "The Effect of Decongestive Nosedrops on Human Respiratory Mucosa In Vitro"
M	E	P.C. Braga et al., J. Pharm. Pharmacol. 44:938-940; 1992 "The effects of calcitonin nasal preparations and their excipients on mucociliary clearance in an ex-vivo frog palate test"
	F	Observations on European Patent Application No. EP 1251867 (third-party observations) <i>No Year</i>

Examiner <i>M</i>	Date Considered 1/26/05
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Examiner Initial	Document Number	Date MM-YYYY	Name	Class	Sub-class	Filing Date If Appropriate
M	US-4,690,952	09-1987	Kagatani, et al.	514	11	Nov. 22, 1985
	US-5,023,252	06-1991	Hseih	514	183	Dec. 8, 1989
	US-5,534,496	07-1996	Lee et al.	514	17	Mar. 29, 1994
	US-5,536,508	07-1996	Canal et al.	424	501	Oct. 21, 1993
	US-5,654,000	08-1997	Poli et al.	424	450	Jul. 17, 1996
	US-5,714,477	02-1998	Einarsson	514	56	Dec. 4, 1995
	US-5,719,122	02-1998	Chiodini, et al.	514	424	Jun. 19, 1995
M	US-5,733,572	03-1998	Unger et al.	424	450	Nov. 29, 1994

FOREIGN PATENT DOCUMENTS

	Document Number	Date MM-YYYY	Country	Class	Sub-class	Translation	
						Yes	No
M	0 371 010	05-1990	Europe				
	0 418 697	03-1991	Europe				
	0 489 217	06-1992	Europe				
M	0 726 075	08-1996	Europe				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

M	G	Remington, The Science and Practice of Pharmacy, 20 th Edition, Philadelphia (USA) Jan. 2000, Chapter 47, pages 922-3
	H	Patent family search for EP 0358 234 (equiv. USP 5,026,825), 1/34/1 Dialog(R) File 351: Derwent abstract, 008189979, "Intranasal calcitonin formulations - contg. Delta-amino-laevulinic acid for enhanced bioavailability". <i>No Year</i>
	I	Patent family search for EP 0327756, 2/34/1 Dialog(R) File 351: Derwent abstract, 007943804, "Pharmaceutical Calcitonin - contg. for nasal glycyrrhizinate to enhance mucosal membrane absorption, esp. for nasal administration". <i>No Year</i>
M	J	Repertorio Farmaceutico Italiano, REFI 4a Edizione (REFI 4 th Edition), 1990, page A 212, ("Calcitonina Spray Nasale Armour", and page A223 "Carbicalcin Spray", Farmindustria, Associazione Nazionale dell'Industria Farmaceutica (National Association of the Pharmaceutical Industry) - CEDOF Editor, 1990
M	K	The Merck Index, 13 th Edition, 2001, page 3576
M	L	Physicians' Desk Reference-PDR 53 Edition 1999, pages 2057-59

Examiner *MATTO*

Date Considered

1/26/05

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U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date MM-YYYY	Name	Class	Sub-class	Filing Date If Appropriate
M	US-5,700,486	12-1997	Canal et al.	424	501	Apr. 30, 1996
	US-5,725,871	03-1998	Illum	424	434	Jun. 15, 1994
	US-5,759,566	06-1998	Poli et al.	424	434	Jun. 17, 1996
	US-6,509,006	01-2003	Platz et al.	424	46	Oct. 26, 1999
	US-6,447,785	09-2002	Donovan	424	239	Nov. 2, 2000
	US-6,440,446	08-2002	Yoshizane et al.	424	423	Apr. 16, 1999
	US-6,440,392	08-2002	Stern	424	43	Feb. 2, 2001
	US-6,348,207	02-2002	Milstein et al.	424	408	Sep. 30, 1997
	US-6,153,582	11-2000	Skelnik	514	12	Nov. 5, 1998
	US-6,086,918	07-2000	Stern et al.	424	474	Mar. 14, 1997
	US-6,017,538	01-2000	Druilhe et al.	424	191	Oct. 18, 1993
	US-5,968,899	10-1999	Sekine et al.	514	3	Jun. 2, 1995
	US-5,938,654	08-1999	Wong et al.	604	892	Feb. 1, 1995
	US-5,912,014	06-1999	Stern et al.	424	474	Mar. 15, 1996
	US-5,858,391	01-1999	Cuca et al.	424	439	May 28, 1997
	US-5,776,886	07-1998	Inamoto et al.	514	2	Jun. 2, 1994
	US-5,726,154	03-1998	Baudys et al.	514	12	Jun. 28, 1996
	US-5,693,608	12-1997	Bechgaard et al.	514	2	Feb. 28, 1995
	US-5,637,309	06-1997	Tajima et al.	424	423	Sep. 20, 1994
	US-5,593,962	01-1997	Arvinte et al.	514	12	Aug. 4, 1993
	US-5,571,788	11-1996	Arvinte et al.	514	12	Jan. 24, 1994
	US-5,496,801	03-1996	Holthuis et al.	514	12	Dec. 23, 1993
	US-5,310,727	05-1994	Lattanzi et al.	514	12	Nov. 30, 1990
M	US-5,281,580	01-1994	Yamamoto et al.	514	12	Jul. 23, 1991

Examiner

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U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date MM-YYYY	Name	Class	Sub-class	Filing Date If Appropriate
M	US-5,279,836	01-1994	Nicolaus	424	484	Jan. 30, 1992
	US-5,234,906	08-1993	Young et al.	514	12	Jan. 10, 1991
	US-4,900,730	02-1990	Miyauchi	514	12	Jun. 18, 1987
	US-4,845,080	07-1989	Fischer	514	12	Sep. 26, 1986
M	US-4,151,276	04-1979	Caulin et al.	424	11	May 12, 1975

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

M	M	Romeijn S.G., et al., INT. J. PHARM., 1996, 135/1-2 (137-145), "The Effect of Nasal Drug Formulations on Ciliary Beating <i>in vitro</i> ", abstract
	N	Schipper N.G.M., et al., CALCIF. TISSUE INT., 1995, 56/4 (280-282), "Methylated (beta)-cyclodextrins are Able to Improve the Nasal Absorption of Salmon Calcitonin", abstract
	O	Marttin E., Pharm. Res., 1997 May, 14 (5): 631-7, "Confocal Laser Scanning Microscopic Visualization of the Transport of Dextrans After Nasal Administration to Rats: Effects of Absorption Enhancers", abstract
	P	Abe K., et al., Chem. Pharm. Bull (Tokyo) 1995 Dec.; 43 (12): 2232-7, "Enhanced Nasal Delivery of Luteinizing Hormone-Releasing Hormone Agonist Buserelin by Oleic Acid Solubilized and Stabilized in Hydroxypropyl-beta-cyclodextrin", abstract
	Q	Kagatani S., et al., Pharm. Res. 1996 13/5 (739-743), "Enhancement of Nasal Salmon Calcitonin Absorption by Lauroylcarnitine Chloride in Rats", abstract
M	R	Morimoto K., et al., J. Pharma. Pharmacol. 1985 37/2 (134-136) "Enhancement of Nasal Absorption of Insulin and Calcitonin Using Polyacrylic Acid Gel", abstract
	S	Casper W.R., et al., Drug & Cosmetic Industry, Vol. 156; No. 1; p. 46, "New Ways of Enhancing the Delivery of Skin Care Ingredients", abstract
	T	Ratafia, Manny, et al., M&M Medical Marketing & Media, Vol 24; No. 11, p. 10, "Drug Delivery: the Key to Biotechnology Markets", abstract <i>NO Year</i>
	U	Biotechnology Newswatch, Vol. 9, No. 12; p. 1, "Two-nasally delivered CalBio hormones pass initial clinicals", abstract
M	V	Marttin E., et al., Pharm Res 1997 May; 14(5) : 631-7, "Confocal laser scanning microscopic visualization of the transport of Dextrans after Nasal Administration to Rats: Effects of Absorption Enhancers", abstract
	W	Kurosaki Y., et al., J. Pharmacobiodyn 1988 Dec; 11 (12) : 824-32, "Application of Propranolol to the Keratinized Oral Mucosa: Avoidance of First-Pass Elimination and the Use of 1-Dodecylazacycloheptan-2-one (Azone) as an Absorption Enhancer of Bioadhesive Film-Dosage Form", abstract
	X	Okamoto H., et al., J. Pharm. Pharmacol 1987 Jul; 39 (7) : 531-4, "Enhanced penetration of mitromycin C through hairless mouse and rats skin by enhancers with terpene moieties", abstract
M	Y	Sugabayashi K., et al., J. Pharm. Pharmacol 1985 Aug; 37 (8) : 578-80, "Effect of the Absorption Enhancer, Azone, on the Transport of 5-Fluorouracil Across Hairless Rat Skin", abstract

Examiner

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M	Z	Vermehren C., et al., Drug Metab Dispos 1997 Sep; 25 (9): 1083-8, "Absorption and Metabolism of the Absorption Enhancer Didecanoylephosphatidylcholine in Rabbit Nasal Epithelium <i>in vivo</i> ", abstract	
	AA	Jacobs M.A., et al., Diabetes 1993, Nov; 41 (11) : 1649-55, "The pharmacodynamics and activity of intranasally administered insulin in healthy male volunteers", abstract	
	BB	Schipper N.G., et al., Pharm Res 1996 Nov; 13 (11) : 1686-92, "Chitosans as Absorption Enhancers for Poorly Absorbable Drugs. 1: Influence of Molecular Weight and Degree of Acetylation on Drug Transport Across Human Intestinal Epithelial (Caco-2) Cells", abstract	
	CC	Pillion D.J., et al., J. Pharm. Sci. 1995 Nov; 84 (11) : 1276-9, "DS-1, A Modified Quillaja Saponin, Enhances Ocular and Nasal Absorption of Insulin", abstract	
	DD	Agerholm C., et al., J. Pharm. Sci. 1994 Dec; 83 (12) : 1706-11, "Epithelial Transport and Bioavailability of Intranasally Administered Human Growth Hormone Formulated with the Absorption Enhancers Didecanoyle-L-alpha-phosphatidylcholine and alpha-cyclodextrin in Rabbits", abstract	
	EE	Critchley H., et al., J. Pharm Pharmacol 1994 Aug; 46 (8) : 651-6, "Nasal Absorption of Desmopressin in Rats and Sheep. Effect of A Bioadhesive Microsphere Delivery System", abstract	
	FF	Santus G., et al., Farmaco 1993 Dec; 48 (12) : 1709-33, "Nasal Formulations of Ketorolac Tromethamine: Technological Evaluation - Bioavailability and Tolerability in Rabbits", abstract	
	GG	Donovan M.D., et al., Pharm. Res. 1990 Aug; 7 (8) : 808-15, "The Molecular Weight Dependence of Nasal Absorption: the Effect of Absorption Enhancers", abstract	
	HH	Pontiroli A.E., et al., Eur J Clin Pharmacol 1989; 37 (4) : 427-30, "Nasal Administration of Glucagon and Human Calcitonin to Healthy Subjects: A Comparison of Powders and Spray Solutions and of Different Enhancing Agents", abstract	
	II	Shao Z., et al., Pharm Res 1992 Sep; 9 (9) : 1157-63, "Cyclodextrins as Nasal Absorption Promoters of Insulin: Mechanistic Evaluations", abstract	
	JJ	Sarkar M.A., Pharm Res 1992 Jan; 9 (1) : 1-9, "Drug Metabolism in the Nasal Mucosa", abstract	
	KK	Morimoto K., et al., Pharm Res 1991 Sep; 8 (9) : 1175-9, "Effects of Proteolytic Enzyme Inhibitors on the Nasal Absorption of Vasopressin and an Analogue", abstract	
	LL	Hosoya K., et al., Biol Pharm Bull 1994 Feb; 17 (2) : 316-22, "Evaluation of Enhancers to Increase Nasal Absorption Using Ussing Chamber Technique", abstract	
M	MM	Tengamnuay P., et al., Pharm Res 1990 Apr; 7 (4) : 370-5, "Bile Salt-Fatty Acid Mixed Micelles as Nasal Absorption Promoters of Peptides. II. <i>In vivo</i> Nasal Absorption of Insulin in Rats and Effects of Mixed Micelles on the Morphological Integrity of the Nasal Mucosa", abstract	
Examiner	<i>Metro</i>	Date Considered	<i>1/26/05</i>
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U.S. PATENT DOCUMENTS (not submitted for applications filed after 6/30/03)

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	US-					
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FOREIGN PATENT DOCUMENTS

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						Yes	No
M	JP 05 078258	03-1993	Japan			Abstract only	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Database WPI, Section Ch, Week 199317, Derwent Publications Ltd., Class 804, AN 1993-140304, XP002300282

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